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Technical and Clinical Success and Long-Term Durability of Endovascular Treatment for Atherosclerotic Aortic Arch Branch Origin Obstruction: Evaluation of 144 Procedures

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WHAT THIS PAPER ADDS

In literature, large series evaluating the mid-term and or long-term results of endovascular treatment for aortic arch branch origin (AABO) obstruction are scarce. This study evaluated the mid-term and long-term results of AABO to show that endovascular treatment of arch branch origin obstruction is a procedure of acceptable safety with good mid-term results.

Objectives: Endovascular treatment of atherosclerotic obstruction of aortic arch branch origins (AABO) has largely replaced open surgery, but long-term outcome data are lacking. This study evaluated mid-term and long-term results of these procedures.

Design: Retrospective cohort study.

Materials and methods: Patients underwent endovascular treatment for symptomatic atherosclerotic stenosis of AABO between 1995 and 2012. Technical success was defined as uncomplicated revascularization and residual stenosis $\leq$30%. The primary end point was freedom from restenosis $\geq$50% on Duplex ultrasonography or magnetic resonance angiography. Secondary end points were freedom from target lesion revascularization or recurrent symptoms.

Results: 144 lesions were treated in 114 patients (75 female; mean age 66.3 years), by percutaneous transluminal angioplasty (PTA) in 20 patients and PTA and stent in 117 patients (brachiocephalic artery [BCA] 9/54; left common carotid artery [LCCA] 0/7; left subclavian artery [LSA] 11/56). The lesion could not be passed in four patients, and in three patients the intervention was terminated before angioplasty. The 30-day technical success was 94.4%, without deaths or strokes. Mean follow-up was 52.0 months (range 2–163 months). Restenosis-free survival was 95.6%, 92.9%, 87.6%, and 83.2% at 12, 24, 48, and 60 months, respectively. Log-rank test showed no significant difference between PTA only and PTA with additional stent placement at any point ($p = .375$), nor between BCA ($n = 51$), LCCA ($n = 6$), or LSA ($n = 57$). During follow-up, 27 patients (23.7%) became symptomatic (15 BCA, 1 LCCA, and 11 LSA); 19 patients with a restenosis of the target lesion (mean 56.7 months). Symptom-free survival was 94.7%, 92.0%, 82.3%, and 77.9% at 12, 24, 48, and 60 months, respectively.

Conclusion: Endovascular treatment of aortic arch branch origin obstruction is safe and efficacious in experienced hands and can be considered as the preferred treatment, with good mid-term durability. Recurrent symptomatic lesions can be treated safely by renewed endovascular means.

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INTRODUCTION

In the general population, the incidence of significant stenosis or occlusion at an aortic arch branch origin (AABO) ranges from 0.5% to 6.4%, with higher occurrence in the brachiocephalic artery (BCA) and left subclavian artery (LSA) compared with the left common carotid artery (LCCA).[1,2] Until 30 years ago, AABO steno-occlusive disease could be treated only with open surgery.[3,4] Despite high long-term

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patency, open surgery has been associated with substantial morbidity and mortality rates.[3,4]

Nowadays, PTA, with or without stenting, is considered feasible and safe and is accepted by most specialists as the first line of treatment for AABO lesions.[3,4] However, reported adverse effects are significant residual stenosis, a high rate of restenosis, and dissection, resulting in limited durability and, ultimately, the need for additional vascular interventions.[5]

Published reports on endovascular treatment of atherosclerotic stenosis or occlusion of the AABO are relatively scarce, with a limited numbers of cases, including only four reports of more than 50 procedures.[2,6–8] Furthermore, these studies are mostly limited to initial success or short-term outcome only. The aim of the present cohort study was to evaluate the mid-term and long-term benefit of endovascular treatment of clinically significant stenosis or occlusion of the AABO.

MATERIALS AND METHODS

Patients and lesions

The study included all patients with symptomatic atherosclerotic lesions of the AABO who received primary endovascular therapy in two large tertiary referral vascular centers in the Netherlands (St. Antonius Hospital, Nieuwegein: 64 patients, 77 interventions, and University Medical Center Utrecht: 50 patients, 67 interventions) between September 1995 and March 2012. The institutional review boards of both hospitals approved this retrospective case cohort analysis.

The initial diagnosis of AABO stenosis or occlusion was based on clinical symptoms and a physical examination. Additional imaging, including duplex ultrasonography (DUS), magnetic resonance arteriography (MRA), and/or computed tomography arteriography (CTA), revealed a ≥50% stenosis or occlusion. The diagnosis of subclavian steal syndrome was based on ipsilateral effort-related fatigue, a blood pressure gradient between the upper extremities, and DUS documented retrograde flow in the vertebral artery (VA) caused by significant stenosis of the subclavian artery.

Inclusion criteria for intervention and the present analysis were symptomatic primary stenosis ≥50% or occlusion at the AABO. All patients and indications for revascularization were discussed in multidisciplinary panels consisting of interventional radiologists, vascular surgeons, and vascular neurologists. Baseline patient characteristics are summarized in Table 1.

Table 1. Summary of patient, lesion, and procedure characteristics.

Patient characteristics	
Total number of patients	114 (100%)
Average age, years	66.3 (range 42–77)
Female	75 (65.8%)
Comorbidity	
Smoker	16 (14.0%)
Hypertension	34 (29.8%)
Hypercholesterolemia	29 (25.4%)
Diabetes mellitus type 2	13 (11.4%)
Preprocedural symptoms	**Total interventions: 144**
TIA	12 (8.3%)
Stroke	1 (0.7%)
Cerebrovascular insufficiency	14 (9.7%)
Amaurosis fugax	35 (24.3%)
Upper limp claudication	52 (36.1%)
Dizziness	26 (18.1%)
Subclavian steal syndrome	5 (3.5%)
Lesion characteristics	**Total interventions: 144**
<50% stenosis	0 (0.0%)
50–70% stenosis	71 (49.3%)
>70% stenosis	68 (47.2%)
Occlusion	5 (3.5%)
Procedure characteristics	**Total interventions: 144**
Technical success	136 (94.4%)
PTA alone	20 (13.9%)
PTA and stent placement	117 (81.2%)
Residual stenosis >30%	1 (0.7%)

Values are given as n (%), unless otherwise stated.
PTA = percutaneous transluminal angioplasty; TIA = transient ischemic attack.

Preinterventional and postinterventional imaging

The preprocedural examination consisted of color-coded DUS, MRA, or CTA of the AABO. At least two imaging studies were performed in 112 of 114 patients to confirm the diagnosis and prepare for an optimal intervention strategy. Also, two imaging studies were performed in all patients receiving endovascular reintervention or re-reintervention. Origin obstruction was defined as an occlusion or stenosis of ≥50% at the transition of the aortic arch to the supra-aortic branch arteries.

A DUS-based peak systolic velocity (PSV) measurement of more than 125 cm/s was the applied threshold for >50% stenosis and a PSV value of 210 cm/s was the threshold for >70% stenosis. Postprocedural imaging at follow-up was performed with DUS. Additional CTA imaging was performed in the event of renewed symptoms and suspicion of (in-stent) restenosis.

Endovascular procedure

All procedures (Fig. 1) were performed in the angiography suite under local anesthesia. Initial arterial access was gained through the common femoral artery with an 8F introduction sheath (Cook Medical Inc., Bloomington, IN, USA). If necessary, a brachial approach was gained through a 4F or 5F introducer sheath.

Angle-tip or straight-tip Terumo guidewires (Terumo Medical, Tokyo, Japan) with a 0.032-inch or 0.035-inch diameter were used to pass the lesion in the supra-aortic arteries. In occlusions, recanalization from a femoral approach was always attempted first. If the lesion could not be crossed, despite the use of selective catheters (e.g. super torque; Cordis, Johnson & Johnson, Fremont, CA, USA) with high support, a combined brachial and femoral approach was used.

When the lesion was passed, balloon angioplasty was performed as a primary angioplasty intervention or as

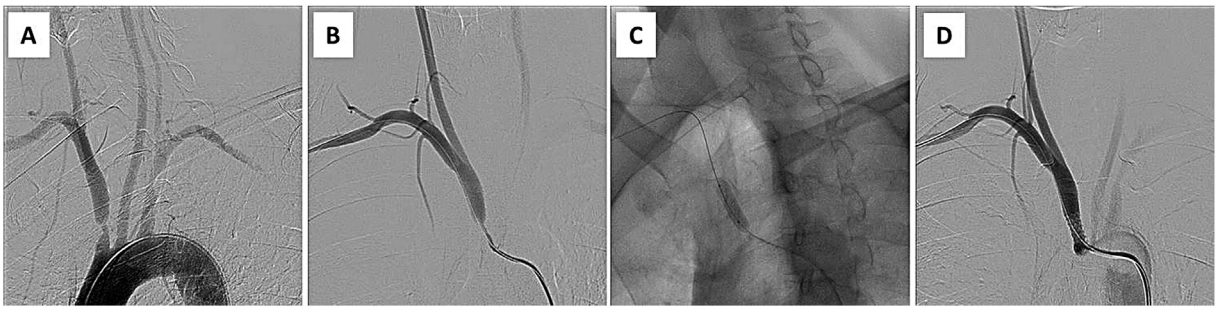

Figure 1. Endovascular treatment of origin stenosis of the brachiocephalic trunk. (A) Digital subtraction angiography of aortic arch in a 52-year-old male with vertebrobasilar insufficiency, showing hemodynamically significant stenosis at the origin of the brachiocephalic trunk. (B) After passing the stenosis a balloon expandable stent (Palmaz Genesis 8 × 24, Cordis Johnson & Johnson, Fremont, CA, USA) is placed. (C) Inflation of the balloon. (D) Control angiography obtained after stent placement.

predilatation before stent placement. PTA with additional stent placement was the primary choice of intervention; however, the decision to use PTA alone or to use an additional stent was determined by the type of lesion (e.g. extent of lesion, residual stenosis, translesion pressure) and rested with the interventionalist performing the procedure.

Different types of stent were used according to personal preference of the interventional radiologist (Table 2). Technical success was defined as a residual diameter reduction of less than 30% on intraprocedural control angiography. Initial clinical success was defined as relief or substantial reduction of the preprocedural symptoms, as listed in Table 1.

End points

The primary end point was defined as freedom from reocclusion or restenosis, defined as a lumen reduction of ≥50% of the target lesion established with DUS.

Secondary end points were defined as freedom from target lesion revascularization (TLR) during follow-up, freedom from adverse cardiovascular events (i.e. composite of death, stroke, myocardial infarction, or residual arm claudication by subclavian steal syndrome), and any other revascularization procedure for aortic arch branch origin stenosis in another target vessel.

Table 2. Stents used by initial intervention.

Stents used	No.
Palmaz Genesis	54
Jomed	19
Express	6
Wall	4
Corinthian	2
Life	2
Unknown	30
Total stent placements	117

Palmaz Genesis: Cordis Johnson & Johnson, Fremont, CA, USA. Jomed: Jomed International AB, Helsingborg, Sweden. Express: Boston Scientific Corporation, Natrick, MA, USA. Wall: Boston Scientific Corporation, Natrick, MA, USA. Corinthian: Cordis Johnson & Johnson, Fremont, CA, USA. Life: Bard Peripheral Vascular, Tempe AZ, USA.

Primary patency was defined as freedom from reintervention of the target lesion during follow-up. Assisted primary patency was defined as patency of the target lesion after endovascular reintervention in case of symptomatic restenosis but without occlusion at any time.

Follow-up

Postoperative clinical evaluation and DUS follow-up was performed at 3 and 12 months after the intervention and annually thereafter. Restenosis was defined as recurrent lumen reduction ≥50% defined by the same DUS threshold criteria as those applied for preintervention imaging.

Statistical analysis

Statistical inferences were made using Kaplan—Meier tests and log-rank tests using IBM SPSS Statistics 20.0 software (IBM Corp, Armonk, NY, USA). A p value of $<.05$ was considered statistically significant. Kaplan—Meier analysis was used to calculate the secondary end point rates. Log-rank tests were used to calculate the difference between secondary end points of PTA only and PTA with additional stent placement. The log-rank test was also used to calculate differences between secondary end points among the BCA, LCCA, and LSA.

RESULTS

Patient and lesion characteristics

Between September 1995 and March 2012, 114 patients (75 female; mean age 66.3 years, range 42—77 years) with significant obstruction of the AABO underwent 144 endovascular interventions (BCA in 67, LCCA in 7, LSA in 70). Preprocedural symptoms are listed in Table 1 and consisted of cerebrovascular insufficiency (e.g. transient ischemic attack, vertebrobasilar insufficiency, stroke, amaurosis fugax, subclavian steal syndrome) or symptoms related to upper limb ischemia. At baseline, all lesions were primary lesions. Preintervention imaging revealed five occlusions (3.5%) and 139 significant stenoses >50% (Table 1).

Procedures

Balloon angioplasty only was performed in 20 lesions (13.9%), and angioplasty with additional stent placement was performed in 117 (81.2%). The lesion could not be passed in four patients, and in three patients the intervention was terminated before angioplasty because of minor complications. The stents used are listed in Table 2. In 124 interventions (86.1%), successful access was gained from the femoral artery approach, whereas in 12 interventions the lesion had to be passed through additional brachial artery access after initial femoral attempts had failed. Brachial artery access was needed because of subtotal ostial stenosis ($n = 10$), and in two interventions because of substantial concomitant aortic arch artery pathology.

In another four lesions (two occlusions and two origin stenosis >70%), the lesion could not be passed by femoral or brachial approach. In one further case, a >30% residual stenosis remained after multiple inflations of the PTA balloon. In three patients minor complications led to termination of the intervention before angioplasty; no PTA was performed in one case because the interventionalist observed plaque extension to the origin of the VA with feared plaque protrusion into the VA origin; in another patient, a perforation with extravasation of the BCA occurred after cannulation, without further sequelae; and the last case was discontinued because of atrial fibrillation, leading to a technical success of 136/144 (94.4%).

Outcome at 30 days

Significant reduction or complete relief of symptoms occurred in 103 of 114 patients, giving a clinical success rate of 90.4%. In four interventions the lesion could not be passed using a femoral or brachial approach, and in another three patients the procedure was terminated before PTA because of minor complications. These three patients were treated conservatively. Four patients with a technically successful procedure had no significant relief or reduction of preprocedural symptoms (dizziness in three; arm claudication in one patient).

Follow-up >30 days

Follow-up examination was performed up to 13.5 years after revascularization, with a mean follow-up time of 52.0 months (range 2—163 months). Of the 114 patients, 12 died at a mean of 28.2 months post procedure (range 6—87 months) of noncardiovascular causes, and one patient declined further follow-up after 24 months. The overall primary patency was 95.6% at 12 months, 92.9% at 24 months, 87.6% at 48 months, and 83.2% at 60 months. The symptom-free survival was 94.7%, 92.0%, 82.3%, and 77.9%, respectively (Fig. 2A). The primary assisted patency was 100%, 99.1%, 98.2%, and 97.3%, respectively (Fig. 2A).

During follow-up, 27 endovascular repeat interventions were performed for AABO restenosis of the BCA (15/67

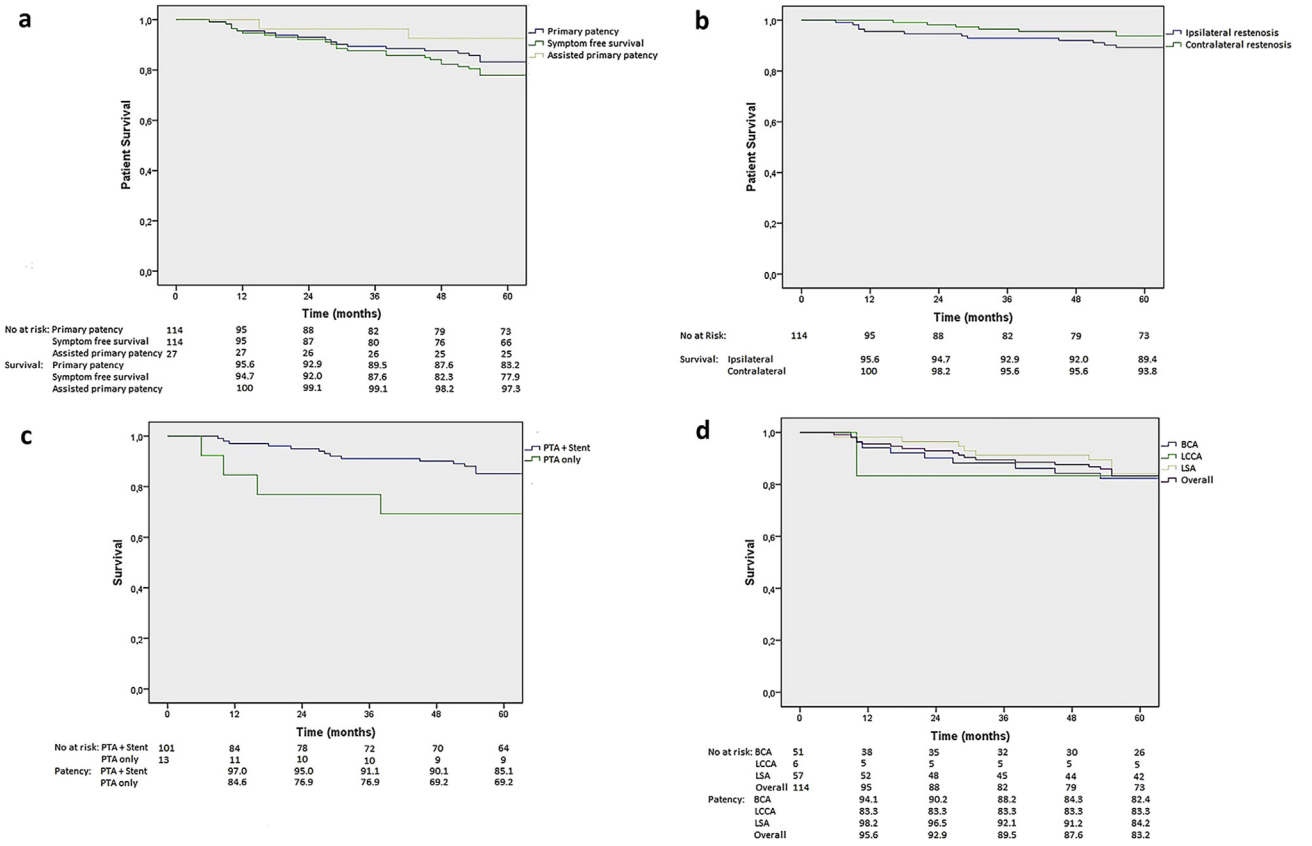

Figure 2. (A) Kaplan—Meier curve shows primary patency, symptom-free survival, and assisted primary patency. (B) Kaplan—Meier curve shows primary patency of ipsilateral and contralateral restenosis. (C) Patency: PTA only versus PTA with additional stent placement. (D) PTA intervention, with or without stent placement, for treatment of origin stenosis of the BCA, LCCA, or LSA, respectively.

[22.4%]), LCCA (1/7 [14.3%]), and LSA (11/70 [15.7%]). Of the 27 endovascular repeat interventions, 19 were performed for recurrent stenosis at the location of the initial target lesion (repeat TLR). As a secondary end point, eight interventions were performed for severe stenosis in a different artery from the original lesion (Fig. 3, Table 3). These 27 procedures were performed in patients with symptomatic presentation. In nine patients, an asymptomatic restenosis of the original target vessel was detected, which was treated conservatively in all cases. All repeat intervention procedures were technically successful.

Overall, 23 of the 27 endovascular reinterventions (85.2%) were PTA with additional stent placement, whereas the initial intervention in the other four was PTA only. Three patients needed more than one reintervention during follow-up (Fig. 4). The primary patency of the repeat TLR was 95.6% at 12 months, 94.7% at 24 months, 92.0% at 48 months, and 89.4% at 60 months. The primary patency of the interventions to treat other AABO arteries was 100%, 98.2%, 95.6%, and 93.8%, respectively (Fig. 2B).

Fig. 2C shows the survival function for PTA-only treatment and the survival function for PTA treatment with additional stent placement. The restenosis-free survival for PTA with additional stent placement was 97.0%, 95.0%, 90.1%, and 85.1%, respectively. The restenosis-free survival for PTA only was 84.6% at 12 months, 76.9% at 24 months, and 69.2% at 48 and 60 months. There was no significant difference in short-term outcome between PTA with stenting and PTA alone, and no significant difference between restenosis-free survival of PTA treatment with or without stent placement ($p = .375$).

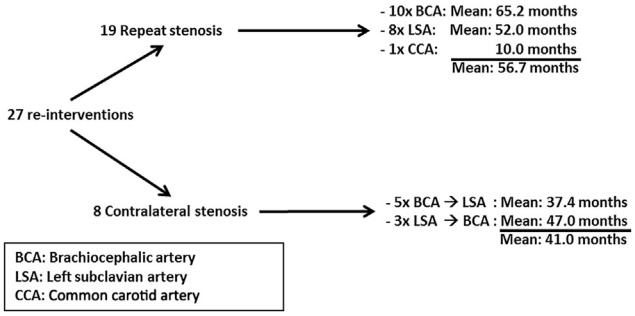

Figure 3. Repeat and alternative interventions.

Table 3. Follow-up >30 days.

Follow-up examination, years	13.5
Follow-up mean (range), months	52.0 (2—163)
Total patients, *n*	114
Death during follow-up, *n*	12
Refused follow-up, *n*	1
Total initial interventions, *n*	114
Total repeat interventions, *n*	27
Total repeat—repeat interventions, *n*	3
Total interventions, *n*	144
Symptomatic during follow-up, *n*	27
Recurrent stenosis, *n*	19
Alternative stenosis, *n*	8

The restenosis-free survival of endovascular PTA treatment, with or without additional stent placement, split for BCA, LCCA, and LSA is projected in Fig. 2D.

Restenosis-free survival for BCA at 12, 24, 48, and 60 months was 94.1%, 90.2%, 84.3%, and 82.4%, respectively, was 83.3% for the LCCA, and was 98.2%, 96.5%, 91.2% and 84.2%, respectively, for the LSA. The overall restenosis-free survival was 95.6%, 92.9%, 87.6% and 83.2%, respectively. The log-rank test between the BCA, LCCA, and LSA showed no significant difference ($p = .473$).

DISCUSSION

In general, there are three methods for treating lesions of the AABO: (1) a transthoracic approach, (2) an extra-thoracic approach, and (3) an endovascular approach.[9,10] The transthoracic approach is associated with significant mortality rates (4.3—8%)[10]; however, despite the significant mortality rate and discomfort, the transthoracic approach has high long-term patency rates.[3,4,9] The extra-thoracic approach seems to have similar patency rates (96% and 88—91% after 1 and 5 years, respectively) with a lower operative mortality rate (0.5—2%).[9,10]

In the present series on endovascular treatment, no periprocedural death occurred and patency rates were 95.6% at 1 year to 83.2% at 5 years, similar to the patency rates of the other two approaches except for the long-term patency. This suggests that the endovascular approach can be safely applied as the first treatment option.

Moreover, it was found that endovascular treatment of AABO obstruction is safe and efficacious in the great majority of treated patients and can be considered as the preferred treatment. The durability of this approach seems acceptable in the mid-term and may be superior with primary stenting. Recurrent symptomatic lesions can be safely treated by endovascular means.

The initial technical success rate in the present study was 94.4%, and the clinical success rate was more than 90% on an intention-to-treat basis. These observations are in line with previous reports; for per protocol PTA with stenting[7] as well as for standardized PTA alone.[8] Of the 114 patients, four had no significant relief of preprocedural symptoms and four lesions could not be passed. Three patients had minor complications according to the Society of Interventional Radiology standards. There were no deaths or permanent neurologic complications.

Large series evaluating the mid-term and/or long-term results of endovascular treatment for AABO obstruction are scarce (Table 4). One study[7] described the results of endovascular treatment of the supra-aortic arteries in 83 patients with a follow-up of almost 5 years. All patients were treated with angioplasty with additional stent placement. This study showed a primary success rate of 94.3% and a primary patency rate of 85.0% at 35 months. The study found with the most interventions reported the results of 131 cases with a mean follow-up of 60 months.[8] All procedures were performed without additional stent placement. The primary success rate was 93.0%, and the

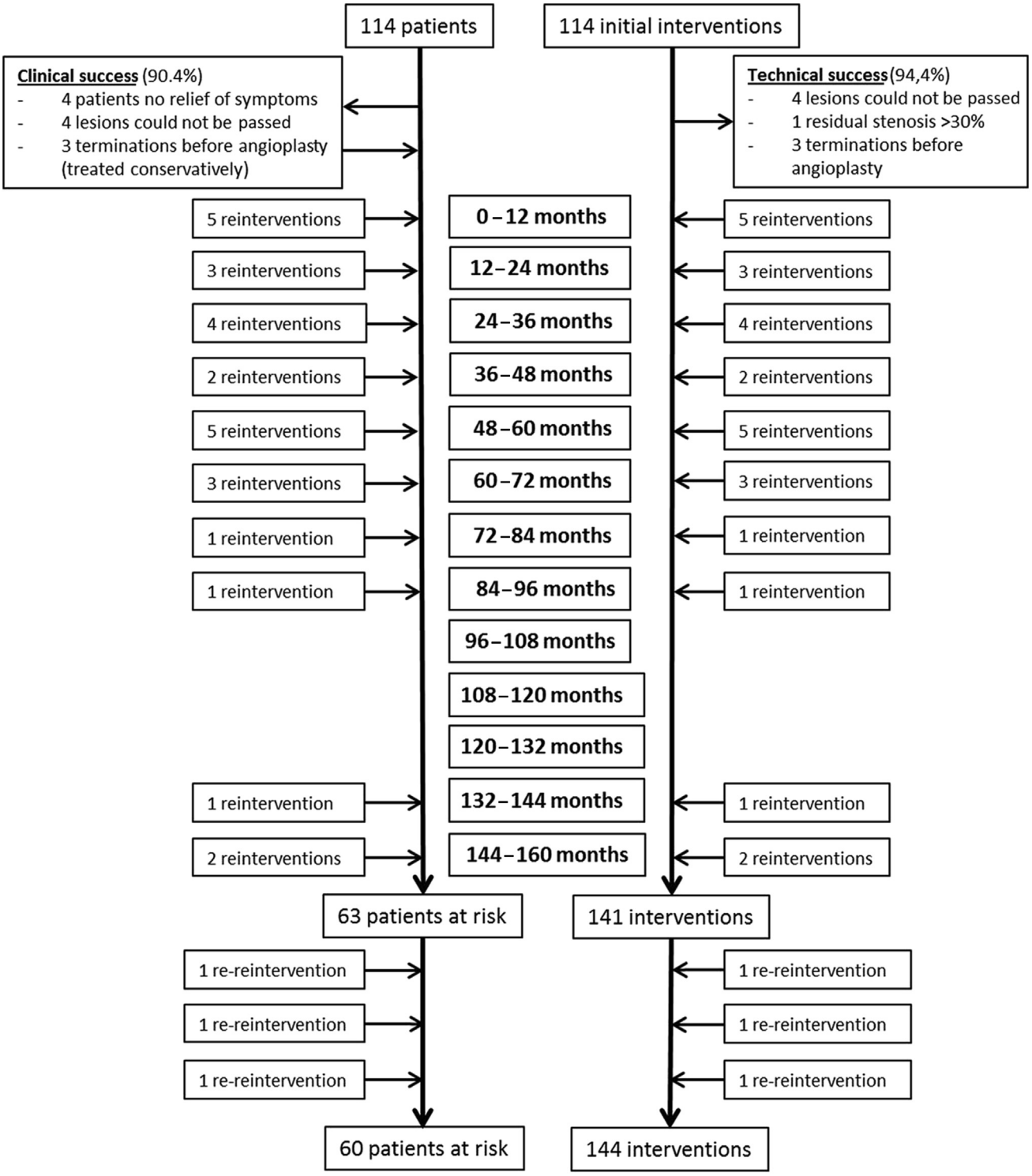

Figure 4. Flowchart of treatment in terms of interventions and number of patients at risk.

primary patency rate of 96.3% at 60 months. These results for PTA alone should be considered as outstanding and unique.

The findings in this comparatively large series suggest that additional primary stent placement after PTA intervention may provide higher primary and secondary patency rates, although no statistical difference could be detected. However, this result is potentially limited by the possibility of bias regarding the nonrandomized preprocedural decision on the endovascular approach, using PTA only versus PTA with stent. The present study revealed that in 10% of all interventions, access was gained through the brachial artery after initial femoral attempts. The brachial approach was initiated because the lesion could not be passed by the femoral approach because of the high degree of stenosis or to aortic arch pathology. This may be of relevance when

Table 4. Literature of endovascular treatment of origin stenoses of supra-aortic arteries.

Author (first author)	Year	Total Int.	Stents, %	Interventions	Symptomatic patients, %	PSR	SR (SR/months)	FU (mean months)
Current study	2014	144	81.3	BCA $n = 67$	100	94.4%	95.6%/12	52.0
				LSA $n = 70$			92.9%/24	
				CCA $n = 7$			83.2%/60	
Muller-Hulsbeck[6]	2007	55	40.0	BCA $n = 7$	100	100	90.6%/20	22.00
				LSA $n = 36$				
				CCA $n = 6$				
				Axillary $n = 5$				
Peterson[11]	2006	20	100	BCA $n = 8$	80	100	100%/1	12
				LSA $n = 3$				
				CCA $n = 9$				
Przewlocki[2]	2005	76	86.8	BCA $n = 2$	85.3	93,4%	88.5%/12	24,4
				LSA $n = 59$			83.6%/24	
				RSA $n = 13$			77.2%/60	
Modarai[12]	2004	35	100	BCA $n = 1$	97.5	85.4%	82.0%/48	48
				LSA $n = 34$				
Gonzales[13]	2002	9	88.9	BCA $n = 2$	100	100%	77.8%/40	37.4
				LSA $n = 7$				
Korner[14]	1999	43	0	BCA $n = 4$	100	84.0%	72.0%/100	15
				LSA $n = 38$				
				LSA—LSA bypass $n = 1$				
Sullivan[7]	1998	87	100	BCA $n = 7$	90.3	94.3%	85.0%/35	14.3
				LSA $n = 66$				
				CCA $n = 14$				
Motarjeme[8]	1993	131	0	BCA $n = 9$		93.0%	96.3%/60	60
				LSA $n = 66$				
				CCA $n = 6$				
				Axillary $n = 3$				
				Brachial $n = 3$				
				Vertebral $n = 35$				
				Internal carotid $n = 7$				
				External carotid $n = 2$				
Selby[15]	1992	32	0	BCA $n = 2$	81.2	100%	96.6%/90	36
				LSA $n = 18$				
				RSA $n = 8$				
				Axillary $n = 4$				

PSR = primary success rate; SR = Survival rate; FU = Follow-up; RSA = right subclavian artery.

informing patients scheduled for endovascular treatment of AABO stenosis.

Patients with symptomatic AABO stenosis are also at substantial risk of developing a stenosis in another AABO. In the present series, based on a total follow-up of 163 months, the risk of new symptomatic lesions developing in a different AABO was 2.3% per year.

This study has several limitations. The main limitation is its retrospective nature. Consecutive case series were collected from two large vascular referral centers, but the caseload during this 17-year period is still limited, without meaningful opportunity to study technical aspects of the procedure or subgroups. However, the largest study[8] published so far reported mid-term outcome, especially showing the risk for future symptomatic arch vessel origin stenosis. Owing to the long period studied (September 1995 until March 2012), the population was not homogeneous. Also, during the study period significant technical advances were made, biasing the results. Follow-up data were missing for 19.0% of the patients. However, documentation was accurate in all patients included, and all DUS reports were accessible on the hospitals' digital databases. Procedural and in-hospital clinical outcomes were available for all 144 interventions. Because of the low incidence of this pathology, a randomized trial of AABO therapy may be beyond expectation.

The lack of significant differences in secondary end point rates in the present study between angioplasty alone and angioplasty with additional stenting and secondary end point rates between the different supra-aortic vessels (Fig. 2C, D) is probably a result of the very small size of the PTA-only group and the inherent selection bias occurring because lesions with less tendency to recoil after PTA are probably over-represented in this group, and these patients are likely to perform better during follow-up.

In conclusion, the present study found that endovascular intervention for primary atherosclerotic occlusive disease of aortic arch branch origin stenosis is a procedure of

acceptable safety with good mid-term results. Most patients with restenosis could be successfully treated with renewed endovascular means. Endovascular treatment should be the preferred treatment in AABO obstruction.

CONFLICT OF INTEREST

None.

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None.

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